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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,468	01/16/2001	Charles S. Munn	81274A	9096

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EXAMINER	
DYE, RENA	

ART UNIT	PAPER NUMBER
3627	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/761,468	Applicant(s) MUNN ET AL.	
	Examiner Rena L. Dye	Art Unit 3627	MW

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-11,13-15,17-21,23,24,27,29,32,43-46 and 51-57* is/are pending in the application.

4a) Of the above claim(s) *2,4,9-11,14,15,20,21,23,24,27,29,43-45,52,54,55 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,6,13,17-19,32,46,51,53 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *16*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 5, 2003 has been entered.

Election of Species

2. In view of Applicant's filing of an RCE and the Examiner's interpretation of the present claims, Applicant's species election in paper no. 9, filed on October 21, 2002, has been reinstated for further examination of the present claims. The examiner has treated the election as follows (repeated from paper no. 10, mailed on January 8, 2003).

Applicant's election of Species Group I - (D) synthetic cis-1,4-polyisoprene and its copolymers and Species Group II - (b) a glove in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant has stated that claims 1,3,5-6,12-13,17-19,32,46,51,53 and 56 are readable on the elected species; however, it is acknowledged that claim 12 has been canceled in the pre-amendment filed on January 16, 2001, and will not be examined with the elected species.

Information Disclosure Statements

3. The Information Disclosure Statement filed on July 15, 2003 has been received; however, a PTO Form 1449 for indication of Examiner consideration has not been included. Applicant has indicated that a PTO Form FB-A820 (?) has been filed; however, it cannot be located in the file. Therefore, the references have not been considered.

The Information Disclosure Statement filed on September 5, 2003 has been received; however, the Japanese references 6-165794, 7-276391, 8-81503 and the article "The New Demand for Shape-Memory Resins in Liquid Form" cannot be located in the file, and have not been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1,3,5-6,13,17-19,32,46,51,53 and 56 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The claimed rubber material having a transition temperature of 94-99 °F is critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

In the present specification Applicant's invention appears to be directed to that which will return to its original size or shape upon heating at or near the human body temperature.

Therefore, "the transition temperature in the range of 94 to 99 degrees Fahrenheit" should be recited accordingly.

Furthermore, the independent claims appear to be much broader in scope with respect to the transition temperature than that taught or suggested by the present specification.

6. Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The term "hypo-allergenic" is not clearly defined in the specification, such that one having ordinary skill in the art would have known how to have made the invention within the meaning of "hypo-allergenic."

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "hypo-allergenic" is indefinite since applicant fails to clearly define the meaning of this term in the present specification.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim 32 is rejected under 35 U.S.C. 102(e) as being anticipated by Beezhold (US 5563241).

Beezhold teaches in the "Background of the Invention" (column 1) that latex comprising about 33% rubber, 65% water and 2% protein, also known as 1,4-cis-polyisoprene is use to make gloves. Although Beezhold teaches that this is naturally occurring, it is the examiner's position that the structure would be identical to that which Applicant is claiming as synthetic. Therefore, the claim has been met.

In claim 32, the preamble limitation hypo-allergenic" is given little or no patentable weight in view of Applicant's failure to clearly define such limitation in the present specification. Further, the recited "consisting essentially" language would not necessarily exclude the proteins taught by Beezhold. Therefore, the rejection has been maintained.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,5,6,13,46 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuan et al. (US 4,891,409).

Kuan et al. teaches a shape transformable composition comprising at least one crystalline polymer and at least one elastomer. The compositions are generally characterized by low glass transition temperatures (<100 °C), fairly compatible polymers and homogenous mixtures (column 1, lines 48-63). The compositions can be shape transformed (stretched or compressed) under heat and retained in the transformed shape by cooling. Upon reheating, the compositions will return, or attempt to return to their original shape (state). Thus, the composition can be stretched or expanded under heat. Upon cooling, the compositions can be retained in the stretched or expanded state or permitted to partially shrink such that a partial expansion of the stretched state is retained. Upon reheating, the composition will shrink or be converted to its original state (column 2, lines 1-18). Suitable elastomers include non-crystalline random amorphous polymers including cis-1,4-polyisoprene either natural or synthetic (column 5, lines 49-59). Generally the crystalline component, the elastomer component, and the cross-linking agents are mixed together and heated to form a desired article.

Applicant's use of "consisting essentially of" claim language is construed as "comprising" language since Applicant has not demonstrated that additional components taught by the Kuan et al. reference would materially change Applicant's claimed invention.

Response to Arguments

10. In view of the reinstatement of rejections of record, the current Examiner will address the arguments set forth in Applicant's response filed on July 11, 2003 as follows:

The Examiner finds Applicant's arguments regarding the rejections of claims under 35 USC § 112, first paragraph, as "a transition temperature of 94-99 °F is critical or essential to the practice of the intention" found at the top of page 8, to not be convincing. Although Applicant does not specifically set forth that the cis-1,4-polyisoprene has a transition temperature of between 94-99 F, it is clear from reading Applicant's present specification that the rubbery products taught by Applicant are intended to shrink at or near human body temperature.

Applicant's attention is directed to page 10, lines 11-17 of the present specification, which discloses that "trans-1,4-polybutadiene is a rubbery material that has a transition temperature very close to 98.6 degrees Fahrenheit, which would make it a very desirable candidate to be used in a condom." Although Applicant has not elected the trans-1,4-polybutadiene, if the species are rejoined and the trans-1,4 polybutadiene species considered for patentability, then there clearly becomes a 112, first paragraph issue regarding the transition temperature.

Applicant's argument "that the gloves warm up to the transition temperature due to body heat alone, externally applied heat, special lighting, X-irradiation, or other methods of effectively heating an object," found at the bottom of page 8, is not convincing. The other methods disclosed by Applicant means just that, other methods; however, such different methods of warming do not necessarily suggest a transition temperature outside that of the 94-99 °F range. Although these methods may be capable of warming to temperatures exceeding 99 °F, it is the

Examiner's position that the rubbery materials, such as trans-1,4 polybutadiene would clearly recover once the rubber material reaches a temperature close to that of human body temperature, as further disclosed in the present specification.

With respect to claim 32, Applicant has failed to clearly define the meaning of "hypo-allergenic", therefore, it is the Examiner's position that such limitation does not clearly patentably distinguish the claim over the teachings of Beezhold. The rejection, therefore, has been maintained.

With respect to "consisting essentially of" language Applicant has not demonstrated that the additional components would materially affect Applicant's claimed invention. In particular, Beezhold teaches a range of proteins from 2-30%. Applicant has not shown that proteinaceous impurities would materially affect the basic and novel qualities of such a glove and render said glove outside the scope of claim 32, especially in the lower end of the range.

If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," Applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).*
Refer to MPEP § 2111.03 (Transitional Phrases).

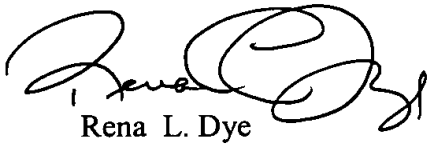
With respect to the rejection of claims 1,5,6,13,46 and 53 under 35 USC 102(b) as being anticipated by Kuan et al., Applicant has not clearly argued or demonstrated that the addition of additional components, such as the crystalline polymer taught by Kuan would materially affect Applicant's claimed invention. The rejection, therefore, has been repeated.

Applicant's filing of a terminal disclaimer July 11, 2003 is acknowledged. Therefore, the double patenting rejection has not been repeated.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rena L. Dye whose telephone number is 703-308-4331. The examiner can normally be reached on Monday-Tuesday 9:00 - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on 703-308-5183. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rena L. Dye
Primary Examiner
Art Unit 3627

R. Dye
February 27, 2004